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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,221	07/27/2005	Christopher Robin Lowe	GJE7140	2605
	23557 7590 03/19/2009 SALIWANCHIK LLOYD & SALIWANCHIK			IINER
A PROFESSIONAL ASSOCIATION			SRIVASTAVA, KAILASH C	
PO Box 142950 GAINESVILLE, FL 32614			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			03/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
Office Action Comments	10/520,221	LOWE ET AL.					
Office Action Summary	Examiner	Art Unit					
	Kailash C. Srivastava	1657					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence add	lress				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 66(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	N. nely filed the mailing date of this cor D (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 25 Au	igust 2008.						
·= · · · · · · · · · · · · · · · · · ·	action is non-final.						
·=	<u> </u>						
,—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)⊠ Claim(s) <u>1-6 and 8-13</u> is/are pending in the app	olication.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-6 and 8-13</u> is/are rejected.	·						
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or	election requirement.						
Application Papers							
9) The specification is objected to by the Examine	•						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Ex	• • • • • • • • • • • • • • • • • • • •		• '				
Priority under 35 U.S.C. § 119							
12) ☐ Acknowledgment is made of a claim for foreign	priority under 25 LLS C S 110(a)	(d) or (f)					
a) All b) Some * c) None of:	priority drider 33 0.3.6. § 119(a)	-(u) or (i).					
1.☐ Certified copies of the priority documents	s have been received						
2. Certified copies of the priority documents		on No					
			Stane				
	3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of		d					
God the attached detailed emice deticition a list of	or the contined copies het reserve	G.					
Attachment(s)	4) The tank to 10 min	(DTO 449)					
1) X Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4)						
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal P						
Paper No(s)/Mail Date	6)						

## **DETAILED ACTION**

1. The response, amendment and remarks filed 25 August 2008 to the Office Action mailed 25 April 2008 is acknowledged and entered.

### **General Informal Matters**

2. The assigned Examiner to the instant application (i.e., US Non-Provisional Application Number (i.e., USSN) 10/520,221 at the United States Patent and Trademark Office (i.e., USPTO) has changed. The assigned Examiner is Kailash C. Srivastava. To aid in correlating any papers for the instant application (i.e., USSN 10/520,221), all further correspondence regarding the instant application (i.e., USSN 10/520,221) should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

### **Claims Status**

- 3. Claims 7 and 14 have currently been cancelled.
- 4. Claims 1 and 8 have currently been amended.
- 5. Claims 1-6 and 8-13 are currently pending and are examined on merits.

# Claim Rejections - 35 U.S.C. §103

6. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).
- 8. Claims 1-6 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al (WO 95126499) as cited in applicants' Information Disclosure Statement (WO 95126499).

In Claims 1-6 and 8-13 is recited a method and a device for detection of a cell, wherein said method comprises immobilizing a cell in a device, said device also containing a sensor, and introducing a growth medium in to said device, wherein the sensor is sensitive to a product of the cell's growth; detecting any change in an optical characteristic of the sensor; wherein the sensor is a holographic sensor. Said cell is a bacterial cell and is immobilized "by means of an antibody".

In response to rejection to Claims 1-6 and 8-13 under 35 U.S.C. § 103(a) as being unpatentable over Lowe et al (WO 95126499) cited *supra* in Office Action mailed 25 April 200; citing a number of case Laws, the presented argument in a lengthy discussion is, "the cited reference does not teach or suggest the claimed invention" (See Remarks filed 25 August 2008, Page 2, Line 8). The salient recited reasons for said conclusion, "does not teach or suggest the claimed invention" (See Remarks filed 25 August 2008, Page 2, Lines 9-28) are as follows:

- i. The present invention requires a growth medium (See Remarks filed 25 August 2008, Page 2, Line 13);
- ii. A holographic support medium performs quite a different function than a growth medium and agar and agarose in context of "Lowe et al. disclosure function only as holographic support media (See Remarks filed 25 August 2008, Page 2, Lines 12-13);
- iii. The Office has given no reason; as to why a skilled artisan would have modified the Lowe et al's method to include introducing a growth medium and immobilizing a cell (See Remarks filed 25 August 2008, Page 2, Lines 15-17)
- iv. "Applicants acknowledge the Examiner's statement regarding result-effective adjustment of particular conventional working conditions, however immobilizing a cell and introducing a growth medium are crucial to the claimed method" (See Remarks filed 25 August 2008, Page 2, Lines 17-19); and
- v. Immobilizing a cell could interfere with a reaction and render the sensor non-functional (See Remarks filed 25 August 2008, Page 2, Lines 25-26).

Regarding applicants' remark cited in item (i) above, both agar and agarose are art-recognized growth media. In particular agar is widely used in microbiological growth media to both grow a variety of

microorganisms and agarose is known for immobilizing microorganisms (see only for reference purposes, e.g., Ray et al., U.S. Patent 5,646,030A, Column 16, Lines 60-66 and Column 18, Lines 33-38).

It is worth noting that in the arguments presented in the remarks filed 25 August 2008 applicants assert that Office has not given any reasoning as to why a skilled artisan would have modified the Lowe et al's method to include introducing a growth medium and immobilizing a cell (See Remarks filed 25 August 2008, Page 2, Lines 15-17). Applicants, however, while arguing, "A holographic support medium performs quite a different function than a growth medium and agar and agarose in context of "Lowe et al. disclosure function only as holographic support media (See Remarks filed 25 August 2008, Page 2, Lines 12-13); have neither explained what function a holographic medium performs, nor why a skilled artisan would not have been modified the Lowe et al's method to include introducing a growth medium and immobilizing a cell given the teachings in the pertinent art for the application of agar for both immobilizing and applying the agar as a growth medium even in a semi-liquid form (known as sloppy afar in the microbiological art). Without such an explanation, it is difficult to understand what applicants are arguing, especially when "applicants acknowledge the Examiner's statement regarding result-effective adjustment of particular conventional working conditions (See Remarks filed 25 August 2008, Page 2, Lines 17-19)

Contrary to applicant' assertion regarding not explaining the reason why an skilled artisan would be motivated to combine Lowe et al's teachings with what is generally known in the pertinent art; in the Office Action mailed 25 April 2008, Examiner has clearly explained those reasons as "Lowe et al particularly teach that the species to be detected may include cells, bacteria, fungi and yeasts, among other analytes" and further as "Lowe et al., beneficially teach that judicious selection of hologram type, fabrication technique and analyte species permits a number of different sensors to be produced, to be tailored to detect specific compounds, events and biological species. Lowe et al., additionally teach that sensitivity of the sensor may be varied by careful choice of specific binding conjugate type of hologram and fabrication techniques used" (See Office Action mailed 25 April 2008, Page 3, Lines 14-21). Furthermore, said reasons are also taught in the Lowe et al (See, Page 11, Lines 15-30). Thus, the teachings in Lowe et al., itself explains why a skilled artisan would be able to modify Lowe et al's teachings to obtain the claimed invention in the instant application, especially the limitation that "sensor is sensitive to a product of the cell's growth because Lowe et al., teach, ", to be tailored to detect specific compounds".

From the discussion presented above, the instant invention would be obvious over the teachings from Lowe et al.

Furthermore, the test for obviousness is not that the claimed invention must be expressly suggested in any one or all of the references. Rather the test is what the teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was made. See *In re Keller* 642. F. 2d 413, 208 USPQ 871 (CCPA 1981). Note that the Examiner-cited reference does not have to teach each and every component in the same order or manner as claimed in the claims under prosecution in the instant application. Furthermore, the 35 U.S.C. §103 statute does not require that the prior art identically disclose or describe Applicants' invention, but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time the invention was made. In this case, given the teachings from Lowe et al., the claimed invention would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made.

Also, a rejection under 35 U.S.C. §103(a) is not deficient solely because the reference is based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

Applicants' arguments cited *supra* have been fully and carefully considered, but are not persuasive for the reasons of record at Pages 2-4 of the Office Action mailed 25 April 2008 and further for the reasons explained in the preceding paragraph. Accordingly, said rejection of Claims 1-6 and 8-13 under 35 U.S.C. §103(a) as being unpatentable over Lowe et al (WO 95126499) in Office Action mailed 07 April 2008 is maintained and adhered to.

### Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

- 10. For the aforementioned reasons, no claims are allowed.
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/ Examiner, Art Unit 1657

Kailash C. Srivastava Patent Examiner Art Unit 1657 (571) 272-0923

14 March 2009 /David M. Naff/ Primary Examiner, Art Unit 1657